DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 1, 2014

VITAL IMAGES, INC.
PARTHIV SHAH
SR. REGULATORY AFFAIRS SPECIALIST
5850 OPUS PARKWAY SUITE 300
MINNETONKA MN 55343

Re: K141302
Trade/Device Name: Vitrea CT Multi-Chamber Cardiac Functional Analysis (CFA)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 2, 2014
Received: July 7, 2014

Dear Mr. Shah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141302

Device Name

Vitrea® CT Multi-Chamber Cardiac Functional Analysis (CFA)

Indications for Use *(Describe)*

The Vitrea® CT Multi-Chamber CFA option is intended to be used with CT studies of the heart to assist cardiologists and radiologists in assessing function when producing a cardiac evaluation. The CT Multi-Chamber CFA option includes semi-automatic heart segmentation including three chambers (left ventricle, right ventricle, and left atrium) segmentation, including identification of long axis and mitral valve boundaries across multiple phases; calculation of global metrics, including end diastolic volume, end systolic volume, stroke volume, ejection fraction, cardiac output, cardiac index, stroke index, and myocardial mass; and calculation of regional metrics; including wall motion, percentage of wall thickening, regional ejection fraction, and polar plots.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(k) Summary

This 510(k) summary is submitted in accordance with the requirements of 21 C.F.R. Part 807.92.(c)

Purpose of Submission: Vital Images, Inc. hereby submits this traditional 510(k) to provide a notification submission of a new software application preset called "CT Multi-Chamber Cardiac Functional Analysis (CFA)". This new application has been added into the Cardiac Functional CT protocol available on the Vitrea platforms to provide cardiac functions of Right Ventricle (RV) and Left Atrium (LA) chambers of heart in addition to the previously cleared cardiac evaluation of Left Ventricle (LV) chamber of heart.

Submitter:
Vital Images, Inc.
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Suite 300
Minnetonka, MN 55343-4414

Establishment Registration: 2134213

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510(k) Type: Traditional

Summary Date: July 2, 2014

Device Name

Trade Name: Vitrea® CT Multi-Chamber Cardiac Functional Analysis (CFA)
Common Name: System, Image Processing, Radiological
Classification Name: System, Image Processing, Radiological (21 C.F.R. 892.2050, LLZ)
Regulatory Description: Picture Archiving and Communications System

Predicate Devices:

Predicate Device	Manufacturer	FDA 510(k) number
Vitrea 2, version 3.7 Medical Image Processing Software – Cardiac Functional Analysis (Legally Marketed Device)	Vital Images, Inc.	K043333
CardIQ Function Xpress (Legally Marketed Device)	GE Medical Systems SCS	K073153

Device Description:
The Vitrea CT Multi-Chamber Cardiac Functional Analysis (CFA) software application is a new post processing licensable software preset available on the Cardiac Functional CT protocol for the Vitrea Platforms. This product can be used in the analysis of CT angiographic images to calculate and display several functional cardiac parameters. The software has the ability to select the chambers of the heart and diastolic and/or systolic phases to evaluate the heart's function. The Vitrea CT Multi-Chamber CFA software application contains both graphic and text report capabilities with predefined templates for ease of use.

Intended Use / Indications for Use:
The Vitrea® CT Multi-Chamber CFA option is intended to be used with CT studies of the heart to assist cardiologists and radiologists in assessing function when producing a cardiac evaluation. The CT Multi-Chamber CFA option includes semi-automatic heart segmentation including three chambers (left ventricle, right ventricle, and left atrium) segmentation, including identification of long axis and mitral valve boundaries across multiple phases; calculation of global metrics, including end diastolic volume, end systolic volume, stroke volume, ejection fraction, cardiac output, cardiac index, stroke index, and myocardial mass; and calculation of regional metrics; including wall motion, percentage of wall thickening, regional ejection fraction, and polar plots.

Intended for Disease / Condition / Patient Population:
The software assists cardiologists and radiologists during a cardiac evaluation to assess various cardiac functions of patients with suspected or known cardiac diseases.

Substantial Equivalence:
The Vitrea CT Multi-Chamber Cardiac Functional Analysis (CFA) software application is substantial equivalent to a combination of the predicate Vital Images, Inc. Cardiac Functional Analysis (K043333) and GE Medical Systems SCS CardIQ Function Xpress (K073153) devices and is safe and effective for use.

Intended Use Comparison:

For Cardiac Evaluation of Left Ventricle (LV) Chamber:

Vitrea CT Multi-Chamber Cardiac Functional Analysis (CFA) (K141302) (Submission Subject)	Vitrea 2, version 3.7 Medical Image Processing Software – Cardiac Functional Analysis (K043333) (Predicate Device-1)	Differences
Intended Use / Indications for Use:		

Vitrea CT Multi-Chamber Cardiac Functional Analysis (CFA) (K141302) (Submission Subject)	Vitrea 2, version 3.7 Medical Image Processing Software – Cardiac Functional Analysis (K043333) (Predicate Device-1)	Differences
The Vitrea® CT Multi-Chamber CFA option is intended to be used with CT studies of the heart to assist cardiologists and radiologists in assessing function when producing a cardiac evaluation. The CT Multi-Chamber CFA option includes semi-automatic heart segmentation including three chambers (**left ventricle**, right ventricle, and left atrium) segmentation, including identification of long axis and mitral valve boundaries across multiple phases; calculation of global metrics, including end diastolic volume, end systolic volume, stroke volume, ejection fraction, cardiac output, cardiac index, stroke index, and myocardial mass; and calculation of regional metrics; including wall motion, percentage of wall thickening, regional ejection fraction, and polar plots.	The CT CFA option is intended to be used with CT studies of the heart to assist cardiologists and radiologists in assessing function when producing a cardiac evaluation. The CFA option includes semi-automatic heart and **left ventricle** segmentation, including identification of long axis and mitral valve boundaries across multiple phases; calculation of global metrics, including end diastolic volume, end systolic volume, stroke volume, ejection fraction, cardiac output, cardiac index, stroke index, and myocardial mass; and calculation of regional metrics; including wall motion, percentage of wall thickening, regional ejection fraction, and polar plots.	The predicate device-1 does not provide cardiac evaluation of right ventricle and left atrium compared to the subject device.
Intended Users:		
Cardiologists and radiologists.	Cardiologists and radiologists.	None
Modality Support:		
CT	CT	None

For Cardiac Evaluation of Right Ventricle (RV) and Left Atrium (LA) Chambers:

Vitrea CT Multi-Chamber Cardiac Functional Analysis (CFA) (K141302) (Submission Subject)	CardIQ Function Xpress (K073153) (Predicate Device-2)	Differences
Intended Use / Indications for Use:		
The Vitrea® CT Multi-Chamber CFA option is intended to be used with CT studies of the heart to assist cardiologists and radiologists in assessing function when **producing a cardiac evaluation**. The CT Multi-Chamber CFA option includes semi-automatic heart segmentation including three chambers (left ventricle, **right ventricle, and left atrium**) segmentation, including identification of long axis and mitral valve boundaries across multiple phases; calculation of global metrics, including end diastolic volume, end systolic volume, stroke volume, ejection fraction, cardiac output, cardiac index, stroke index, and myocardial mass; and calculation of regional metrics; including wall motion, percentage of wall thickening, regional ejection fraction, and polar plots.	CardIQ Function Xpress is intended to provide an optimized noninvasive application **to analyze cardiovascular anatomy and pathology** and aid in determining treatment paths from a set of Computed Tomography (CT) Angiographic images. CardIQ Function Xpress in conjunction with CT cardiac images to automatically calculate and display various left ventricular and **right ventricular functional parameters** as ejection fraction, end systolic and end diastolic volumes, stroke volumes, wall motion, wall thickening, cardiac output, myocardial mass, systemic and pulmonary vascular resistance. **Volume measurement of each chamber of the heart is also available**. With CardIQ Function Xpress atrium volumes may be used to determine volume assessment of atrial disease to include but not limited to atrial fibrillation. CardIQ Function Xpress is a CT, non-invasive image analysis software package, which aids in the assessment of cardiac function and in determination of cardiovascular disease diagnosis and management. CardIQ Function Xpress is for use on the Advantage Workstation (AW) platform, CT Scanner, PAC or Centricity stations, which can be used in the analysis of 2D or 3D CT angiography images/data derived from DICOM 3.0 CT scans.	None

Vitrea CT Multi-Chamber Cardiac Functional Analysis (CFA) (K141302) (Submission Subject)	CardIQ Function Xpress (K073153) (Predicate Device-2)	Differences
Intended Users:		
Cardiologists and radiologists.	Cardiologists and radiologists.	None
Modality Support:		
CT	CT	None

Technological Characteristics Comparison:

Characteristic	(Submission Subject)	(Predicate Device-1)	(Predicate Device-2)	Differences
	Vitrea CT Multi-Chamber Cardiac Functional Analysis (CFA)	Vitrea 2, version 3.7 Medical Image Processing Software – Cardiac Functional Analysis	CardIQ Function Xpress	
		For Cardiac Evaluation of Left Ventricle (LV) Chamber	For Cardiac Evaluation of Right Ventricle (RV) and Left Atrium (LA) Chambers	
	(K141302)	(K043333)	(K073153)	
Device Description:				
Input Data:				

Characteristic	(Submission Subject)	(Predicate Device-1)	(Predicate Device-2)	Differences
	Vitrea CT Multi-Chamber Cardiac Functional Analysis (CFA)	Vitrea 2, version 3.7 Medical Image Processing Software – Cardiac Functional Analysis	CardIQ Function Xpress	
		For Cardiac Evaluation of Left Ventricle (LV) Chamber	For Cardiac Evaluation of Right Ventricle (RV) and Left Atrium (LA) Chambers	
	(K141302)	(K043333)	(K073153)	
Use in the analysis of CT angiographic images to calculate and display analysis of several functional cardiac parameters	Yes	Yes	Yes	None
DICOM 3.0 compliant image data	Yes	Yes	Yes	None
Where Used:				
Medical facility	Yes	Yes	Yes	None
User Interface:				
Designed for use on a radiology workstation	Yes	Yes	Yes	None
Loading DICOM Datasets:				
Processes multi-phase, multi-slice cardiac CT images	Yes	Yes	Yes	None

Characteristic	(Submission Subject)	(Predicate Device-1)	(Predicate Device-2)	Differences
	Vitrea CT Multi-Chamber Cardiac Functional Analysis (CFA)	Vitrea 2, version 3.7 Medical Image Processing Software – Cardiac Functional Analysis	CardIQ Function Xpress	
		For Cardiac Evaluation of Left Ventricle (LV) Chamber	For Cardiac Evaluation of Right Ventricle (RV) and Left Atrium (LA) Chambers	
	(K141302)	(K043333)	(K073153)	
Provides ability to select Diastolic phase	Yes	Yes	Yes	None
Provides ability to select Systolic phase	Yes	Yes	Yes	None
Automatically identifies the long axis across multiple phases	Yes	Yes	Yes	None
Automatically identifies the plane of the Mitral valve	Yes	Yes	Yes	None
Segmentation:				
Semi-automatic segmentation of Left Ventricle (LV) chamber	Yes	Yes	Yes	None
Semi-automatic segmentation of Myocardium of Left Ventricle (LV) chamber	Yes	Yes	Yes	None

Characteristic	(Submission Subject)	(Predicate Device-1)	(Predicate Device-2)	Differences
	Vitrea CT Multi-Chamber Cardiac Functional Analysis (CFA)	Vitrea 2, version 3.7 Medical Image Processing Software – Cardiac Functional Analysis	CardIQ Function Xpress	
		For Cardiac Evaluation of Left Ventricle (LV) Chamber	For Cardiac Evaluation of Right Ventricle (RV) and Left Atrium (LA) Chambers	
	(K141302)	(K043333)	(K073153)	
Key Functions:				
Automatic determination of End Diastolic (ED) and End Systolic (ES) phases by volume	Yes	Yes	Yes	None
Volume Rendering	Yes	Yes	Yes	None
Phase Navigator	Yes	Yes	Yes	None
Semi-automatic determination of Epicardial and Endocardial contours	Yes	Yes	Yes	None
Automated Calculation of Cardiac Parameters				
End Diastolic Volume (EDV)	Yes	Yes	Yes	None
End Systolic Volume (ESV)	Yes	Yes	Yes	None

Characteristic	(Submission Subject)	(Predicate Device-1)	(Predicate Device-2)	Differences
	Vitrea CT Multi-Chamber Cardiac Functional Analysis (CFA)	Vitrea 2, version 3.7 Medical Image Processing Software – Cardiac Functional Analysis	CardIQ Function Xpress	
		For Cardiac Evaluation of Left Ventricle (LV) Chamber	For Cardiac Evaluation of Right Ventricle (RV) and Left Atrium (LA) Chambers	
	(K141302)	(K043333)	(K073153)	
Stroke Volume (SV)	Yes	Yes	Yes	None
Stroke Index (SI)	Yes	Yes	Yes	None
Ejection Fraction (EF)	Yes	Yes	Yes	None
Cardiac Output (CO)	Yes	Yes	Yes	None
Myocardial Mass	Yes	Yes	Yes	None
Wall Motion	Yes	Yes	Yes	None
Percent Wall Thickening	Yes	Yes	Yes	None
Myocardial Volume (MV)	Yes	Yes	Yes	None
Myocardial Index	Yes	Yes	Yes	None

Characteristic	(Submission Subject)	(Predicate Device-1)	(Predicate Device-2)	Differences
	Vitrea CT Multi-Chamber Cardiac Functional Analysis (CFA)	Vitrea 2, version 3.7 Medical Image Processing Software – Cardiac Functional Analysis	CardIQ Function Xpress	
		For Cardiac Evaluation of Left Ventricle (LV) Chamber	For Cardiac Evaluation of Right Ventricle (RV) and Left Atrium (LA) Chambers	
	(K141302)	(K043333)	(K073153)	
Myocardial Mass Index	Yes	Yes	Yes	None
Regional Ejection Fraction (EF)	Yes	Yes	Yes	None
Outputs a Polar Map	Yes	Yes	Yes	None
Time/Volume Graph	Yes	Yes	Yes	None
Views:				
2D image viewing with real-time Window/Level, Zoom, and Pan	Yes	Yes	Yes	None
3D and Multi-Planar Reformatting (MPR) view	Yes	Yes	Yes	None
Maximum Intensity Projection	Yes	Yes	Yes	None

Characteristic	(Submission Subject)	(Predicate Device-1)	(Predicate Device-2)	Differences
	Vitrea CT Multi-Chamber Cardiac Functional Analysis (CFA)	Vitrea 2, version 3.7 Medical Image Processing Software – Cardiac Functional Analysis	CardIQ Function Xpress	
		For Cardiac Evaluation of Left Ventricle (LV) Chamber	For Cardiac Evaluation of Right Ventricle (RV) and Left Atrium (LA) Chambers	
	(K141302)	(K043333)	(K073153)	
Automatic industry standard Oblique views of the heart	Yes	Yes	Yes	None
Tools:				
Provides image editing tools if adjustments are needed	Yes	Yes	Yes	None
Visualization presets and automated steps for typical image review procedures	Yes	Yes	Yes	None
Report	Yes	Yes	Yes	None
Printing: Printing to standard Windows or DICOM printers	Yes	Yes	Yes	None

Characteristic	(Submission Subject)	(Predicate Device-1)	(Predicate Device-2)	Differences
	Vitrea CT Multi-Chamber Cardiac Functional Analysis (CFA)	Vitrea 2, version 3.7 Medical Image Processing Software – Cardiac Functional Analysis	CardIQ Function Xpress	
		For Cardiac Evaluation of Left Ventricle (LV) Chamber	For Cardiac Evaluation of Right Ventricle (RV) and Left Atrium (LA) Chambers	
	(K141302)	(K043333)	(K073153)	
Export / Restore Findings	Yes	Yes	Yes	None

Additional Similarity with Predicate Device-1:

Cardiac Parameter	Vitrea CT Multi-Chamber Cardiac Functional Analysis (CFA) (K141302) (Submission Subject)	Vitrea 2, version 3.7 Medical Image Processing Software – Cardiac Functional Analysis (K043333) (Predicate Device-1)	Differences
Cardiac Index (CI)	Yes	Yes	None

The above characteristic is the same characteristics as found in the available predicate device-1 (K043333).

Additional Similarity with Predicate Device-2:

Characteristic	Vitrea CT Multi-Chamber Cardiac Functional Analysis (CFA) (K141302) (Submission Subject)	CardIQ Function Xpress (K073153) (Predicate Device-2)	Differences
Semi-automatic segmentation of Right Ventricle (RV) chamber	Yes	Yes	None
Semi-automatic segmentation of Left Atrium (LA) chamber	Yes	Yes	None
Maximum Volume	Yes	Yes	None
Review Heart in Motion	Yes	Yes	None

Differences from the Predicate Devices:

Cardiac Parameter	(Submission Subject) (K141302)	(Predicate Device-1) (K043333)	(Predicate Device-2) (K073153)	Test
	Vitrea CT Multi-Chamber Cardiac Functional Analysis (CFA)	Vitrea 2, version 3.7 Medical Image Processing Software – Cardiac Functional Analysis	CardIQ Function Xpress	
		For Cardiac Evaluation of Left Ventricle (LV) Chamber	For Cardiac Evaluation of Right Ventricle (RV) and Left Atrium (LA) Chambers	
Regurgitation Fraction	Yes	No	Information not available	The additional measurement is verified by an internal test.
Cyclic Volume Change	Yes	No	Information not available	The additional measurement is verified by an internal test.
Reservoir Volume	Yes	No	Information not available	The additional measurement is verified by internal tests.

Description of the added features to the Predicate Device-1 (K043333):

The new features added to the predicate device-1 (K043333) since the clearance are defined as follows:

- The predicate device-1 (K043333) provides cardiac evaluation for the Left Ventricle (LV) chamber of heart. The subject device is an extension of the predicate device-1 (K043333) with additional support for cardiac evaluation of the Right Ventricle (RV) and Left Atrium (LA) chambers of the heart.

- The technical characteristics for the predicate device-1 (K043333), which are defined in the technical characteristics comparison table, are the same characteristics which now have been added in the subject device for the Right Ventricle (RV) and Left Atrium (LA) chambers of the heart.

  The technical characteristics that have been added for the Right Ventricle (RV) and Left Atrium (LA) chambers of the heart are the same characteristics currently available for the Left Ventricle (LV) and carry the same risk profile as the predicate device-1 (K043333). Therefore, these additions do not raise new safety and efficacy concerns when used as labeled.

- In addition, there are seven (7) characteristics which have been added. These additions are:
  - Semi-automatic segmentation of Right Ventricle (RV) chamber
  - Semi-automatic segmentation of Left Atrium (LA) chamber
  - Maximum Volume
  - Review Heart in Motion
  - Regurgitation Fraction
  - Cyclic Volume Change
  - Reservoir Volume

The above noted additional seven characteristics either do not carry hazardous risks or are not critical to the risk profile based on an "Improbable" probability of occurrence of harm after applied mitigations. The above noted additional seven characteristics have been mitigated by design, labeling, and performed verification and validation tests and therefore do not raise new safety and effectiveness concerns when used as labeled.

Summary of Non-Clinical Tests:
The software was designed, developed and tested according to written procedures that included applying risk management. Software testing was completed to ensure the new feature operates according to its requirements. Testing included verification, validation, and evaluation of previously acquired medical images.

The following quality assurance measures were applied to the development of Vitrea CT Multi-Chamber Cardiac Functional Analysis (CFA) software application:

- Risk Management
- Requirements reviews
- Developer testing
- Code reviews
- Design reviews
- Verification of the software – that included performance and safety testing
- Validation of the software – that included simulated usability testing by independent experienced medical professionals.

Risk Management:
Vital Images performed a risk analysis, referring to software hazards associated with the intended use, including severity assessment and mitigation. The analysis was based upon the application of ISO 14971:2012 Risk Management to Medical Devices, in compliance with medical device ISO 13485:2012 and IEC 62304:2006 requirements.

All identified risks were reduced as low as possible. The medical benefits of the software outweigh the residual risk for each individual risk and all risks together. The overall residual risk for the software was deemed acceptable.

Verification:
The software verification team's primary goal was to assure that the software fully satisfies all expected system requirements and features. Test cases were executed against the system features and requirements. As a part of

creating the test cases, the verification team reviewed and monitored the Requirements Traceability Matrix ("RTM") to ensure coverage of the items within the RTM.

Validation:

The software validation team's primary goal was assuring the software conforms to user needs and intended use. The validation team conducted workflow testing that provided evidence that the system requirements and features were implemented, reviewed and met.

External Validation:

During external validation of Vitrea CT Multi-Chamber Cardiac Functional Analysis (CFA) software application, experienced cardiologists evaluated the application. Each user felt that the Vitrea CT Multi-Chamber Cardiac Functional Analysis (CFA) software application can be used successfully with CT studies of the heart to assist cardiologists and radiologists in assessing function when producing a cardiac evaluation.

Summary of Clinical Tests:

The subject of this traditional 510(k) notification, Vitrea CT Multi-Chamber Cardiac Functional Analysis (CFA) software application, did not require clinical studies to support safety and effectiveness of the software.

Cyber and Information Security:

- ***Confidentiality***
  The Vitrea platform relies on built in Windows Login security to limit access to the system. The Vitrea platform can only be installed and configured by an administrator of the Windows machine.

- ***Integrity***
  The Vitrea platform complies with the DICOM standard for transfer and storage of this data and does not modify the contents of DICOM instances. The Vitrea platform identifies the data it produces, marking and encoding the appropriate DICOM fields.

- ***Availability***
  The Vitrea platform is always available to the logged on user as long as the Windows machine itself is properly maintained.

- ***Accountability***
  The Vitrea platform includes an audit capability that enables accountability by tracking authenticated and authorized user operations along with information accessed. Vitrea audit logs are time stamped, enabling correlation with Windows system logging to track information accessed by a user.

Performance Standards:

The FDA has not established mandatory performance standards and no special controls exist for this device. General software verification and validation tests were conducted to confirm proper function of the device's features.

The Vitrea CT Multi-Chamber Cardiac Functional Analysis (CFA) software application complies with the following voluntary recognized consensus standards:

Standard No.	Standards Organization	Standard Title	Version	Date
PS 3.1- 3.20 (2011) (Recognition Number 12-238)	NEMA	Digital Imaging and Communications in Medicine (DICOM) Set (Radiology)	3	03/16/2012

Standard No.	Standards Organization	Standard Title	Version	Date
ISO 14971:2007 (Recognition Number 5-70)	AAMI / ANSI / ISO	Medical Devices - Applications of Risk Management to Medical Devices	2007	03/16/2012
IEC 62304:2006 (Recognition Number 13-32)	AAMI / ANSI / IEC	Medical Device Software - Software Life Cycle Processes (Software / Informatics)	2006	08/20/2012

Conclusion:
Vital Images believes that Vitrea CT Multi-Chamber Cardiac Functional Analysis (CFA) software application has a substantially equivalent intended use, indications for use and technological characteristics as the predicate devices. Any minor differences noted have been explained and do not raise any new questions of safety or effectiveness when used as labeled. The implemented design mitigations, labeling, and the performed verification and validation tests demonstrate the safety and efficacy of the device is equivalent to the predicate devices. Based on the comparison data and test data, Vital Images believes the subject device should be found substantially equivalent to the predicate devices.